C3 cont'd

a) culturing a host cell transformed with an [expressing] expression vector comprising a nucleic acid according to claim 1 [encoding a DRG11 protein]; and

b) expressing said nucleic acid to produce a DRG11 protein.

Remarks

Claims 1-2 and 4-7 are under consideration in this case. An appendix with these claims as amended is provided for the Examiner's convenience.

REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 1-2 and 5-7 are rejected under 35 U.S.C. §112, first paragraph, as being non-enabled. Applicants respectfully traverse.

Applicants have amended the claims to further define both the claimed nucleic acid and the protein which the nucleic acid encodes. Support for the amendments are found on page 7, lines 21-26, and page 31, lines 4 and 22-23.

Applicants submit that provided with the nucleic acid sequence of SEQ ID NO:1, as well as the expression pattern of naturally expressed DRG11 as recited in claim 1 (see page 31 of the specification for support), one skilled in the art could routinely identify the claimed invention.

Regarding "how to use" the invention, which is the focus of the Office Action, Applicants submit that the specification provides sufficient disclosure to meet this

requirement for patentability. Specifically, the Office Action focuses on whether the inherent functions of DRG11 are disclosed in the specification and whether the disease states which may be treated with DRG11 are disclosed in the specification. However, these inquiries need not be addressed at this time.

Applicants respectfully draw the Examiner's attention to the claim language. The claims are drawn to nucleic acids. The present claims are not drawn to a method of treating a disease state, and therefore, a determination of support for such claims need not be made.

Regarding the statement in the Office Action reciting that Applicants have not enabled how to use "the full scope of the claimed invention", Applicants submit that only one reasonable use of the invention need be disclosed to fulfil the "how to use" requirement as set forth in the new utility guidelines (which are also applied to the enablement requirement). There is no requirement that more than one use, particularly not each and every use of the full scope of the invention, be disclosed to fulfill the "how to use" requirement.

In this regard, Applicants have provided a number of uses for the claimed invention including the use of the encoded protein as a marker to identify neurons in the peripheral sensory lineage. The claims clearly set forth an expression pattern for the protein which enables the encoded protein to be used as such a marker. Therefore, the "how to use" requirement for patentability has been fulfilled. Moreover, Applicants further add that the PTO's current policy toward allowing the patentability of open reading frames based on the

use of nucleic acids as probes and as templates for encoding proteins is applicable in the present case, which is drawn to nucleic acids. Therefore, Applicants respectfully submit that the "how to use" requirement for patentability has been fulfilled and request that the rejection be withdrawn.

REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claim 2 is rejected under 35 U.S.C. §112, second paragraph, as failing to particularly and distinctly claim the subject matter regarded as the invention. Applicants respectfully traverse.

Applicants have amended Claim 2 to recite a sequence identifier for the amino acid sequence as recited, rather than a nucleic acid sequence. Regarding the term "isolated", Applicants submit that the term "recombinant" accurately describes the invention, however, for further clarity, Applicants have replaced the term "recombinant" with "isolated". Applicants therefore respectfully request that the rejection be withdrawn.

REJECTIONS UNDER 35 U.S.C. §102

Claims 1-6 are rejected under 35 U.S.C. §102(b) as anticipated by Saito, et al., Acc. No. U29174 (Saito), Liu, et al., Neuron, 13:377-393 (1994) (Liu) or Cserjesi, et al., Development, 115:1087-1101 (1992) (Cserjesi). Applicants respectfully traverse.

Saito is not prior art

The Office Action states that Saito discloses the claimed sequence and was submitted to Genbank June 14, 1995. The Office Action further states that absent evidence to the contrary, it can be assumed that the sequence was "released" or publicly available within a period of weeks.

First, Applicants point out that the present application claims priority to its parent, U.S. Serial No. 60/023,280, filed July 25, 1996. Applicants submit that the one year date prior to this date, falls within "weeks" of June 14, 1995.

Second, Applicants submit that the "release of data" from Genbank took place on February 10, 1996 as shown in the second line (right) of Saito. As Saito must have been publicly available for more than one year prior to Applicants' filing date to be anticipatory art, and since February 10, 1996 is within one year of Applicants' filing date, Saito is not prior art. Applicants therefore respectfully request withdrawal of the rejection.

Liu does not disclose or suggest the claimed invention

The Office Action points out that Liu has a stretch of 40 nucleotides which align (with two mismatches) with 40 nucleotides of the 2400+ nucleotides of SEQ ID NO:1. Liu reports on a gene which may have a role in determination of the neuroretina and inner nuclear layer. Liu reports on several expression patterns, including initial expression in the ventricular zone in the ventral half of the spinal cord (page 385, right).

The claims have been amended to clarify that DRG11 is not naturally expressed in the ventral spinal cord. See, page 31, line 23 of the specification for support. Therefore Liu does not disclose the claimed invention. Moreover, the skilled artisan would not be led to the claimed invention from Liu, since Liu discloses a natural expression pattern which differs from that recited in the claims. Applicants therefore, respectfully request that the rejection be withdrawn.

Csejesi does not disclose or suggest the claimed invention

The Office Action points out that Cserjesi has a stretch of 51 nucleotides which align (with four mismatches) with 51 nucleotides of the 2400+ nucleotides of SEQ ID NO:1. Cserjesi reports on a mesodermally restricted homeodomain protein.

The claims have been amended to further define the claimed subject matter by its natural expression patterns. Specifically, expression is absent in non-neuronal cells. Cserjesi reports on a protein which acts in cell types of mesodermal origin. Mesodermal origin cell types include those in muscle, bone, connective tissue and the inner skin layer, in contrast to neurons originating from the neural crest. Therefore, the skilled artisan would not arrive at the present invention from the teachings of Cserjesi. Thus, Cserjesi not only does not disclose the claimed invention, Cserjesi does not suggest the claimed invention. Applicants, therefore, respectfully request withdrawal of the rejection.

For all the foregoing reasons, Applicants respectfully submit that the Claims are in condition for allowance and such allowance is earnestly solicited. If any issues which

APPENDIX--

1. (Amended) [A recombinant] An isolated nucleic acid encoding a DRG11 protein, wherein said nucleic acid hybridizes under high stringency conditions to a complement of a nucleic acid molecule having a sequence as set forth in SEQ ID NO:1, and wherein said DRG11 protein is characterized by its natural expression in sensory neurons and dorsal horn neurons of the spinal cord and wherein its natural expression is absent in non-neuronal cells, sympathetic neurons and ventricular neurons of the spinal cord.

2. (Twice Amended) [A recombinant] An isolated nucleic acid according to claim 1 encoding the amino acid sequence depicted in Figure 3 (SEQ ID NO:2) [2 (SEQ ID NO:1)].

4. (Twice Amended) [A recombinant] An isolated nucleic acid according to claim 1 comprising the nucleic acid depicted in Figure 2 (SEQ ID NO:1).

5. (Amended) An isolated nucleic acid according to claim 1 operably linked to an [An] expression vector comprising transcriptional and translational regulatory DNA [operably linked to DNA encoding a DRG11 protein].

6. A host cell transformed with an expression vector according to claim 5.

7. (Amended) A method of producing a DRG11 protein comprising:

a) culturing a host cell transformed with an [expressing] expression vector comprising a nucleic acid according to claim 1 [encoding a DRG11 protein]; and

b) expressing said nucleic acid to produce a DRG11 protein.

preclude allowance remain, please call the under-signed at (415) 781-1989 to resolve such issues.

Respectfully submitted,

FLEHR HOHBACH TEST
ALBRITTON & HERBERT LLP

Dolly A. Vance
Reg. No. 39,054

Four Embarcadero Center, Suite 3400
San Francisco, CA 94111-4187

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